



NRC Vendor Inspection Activities

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Topic Areas

- Office of New Reactors (NRO) Vendor Inspection Program
- NRC Vendor Inspections
- NUPIC Audit Observations
- International Cooperation
- Commercial Grade Calibration Services
- NRC/NQA-1 Interactions
- Generic Communications

NRO Vendor Inspection Program

- Commission Paper (SECY-07-0105):
Enhancement to the Vendor Inspection Program
Within the Office of New Reactors
 - To inform the Commission that NRO is enhancing the Vendor Inspection Program (VIP) in support of new reactor licensing and construction
 - To describe these enhancements, including the development of program guidance and an anticipated increase in audit and inspection activities.

NRO Vendor Inspection Program

- Significant factors that led to expanded oversight of nuclear component suppliers include:
 - the entry of new suppliers to the U.S. nuclear industry (domestic and international)
 - the use of modular construction techniques
 - engineering and licensing support services to most applicants
 - ITAAC verification (relate vendor inspections to ITAAC Families)

NRO Vendor Inspection Program

- Inspection Manual Chapter (IMC) 2507 – Construction Vendor Inspection Program for New Reactors
 - **Inspection Procedure (IP) 43002:** Routine Inspections of Nuclear Vendors
 - **IP 43003:** Reactive Inspections of Nuclear Vendors
 - **IP 43004:** Inspection of Commercial Grade Dedication Programs
 - **IP 43005:** NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements
 - **IP 36100:** Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance

Vendor Inspection Activities

- Completed Vendor Inspections
 - Veridiam, Inc., 6/2007
 - Target Rock, Inc., 6/2007
 - Conval, Inc., 8/2007
 - Babcock & Wilcox Canada, 8/2007
 - Velan, Inc., 9/2007
 - AREVA NP, 10/2007
 - AREVA NP (Eaton Cutler-Hammer), 10/2007
 - University of Texas, 10/2007
 - Tioga Pipe Supply Company, Inc., 3/2008
 - AREVA NP (GmbH), 3/2008
 - Namco Controls, 4/2008
 - PCI Energy Services, 5/2008
 - Mitsubishi Heavy Industries, 5/2008
 - Doosan Heavy Industries, 5/2008
 - Invensys Triconex, 5/2008

Notices of Violation

- **10 CFR Part 21:**

- Failure to develop an appropriate 10 CFR Part 21 procedure to:
 - Evaluate deviations and failures to comply associated with substantial safety hazards
 - Include an interface between the corrective action reporting processes and the Part 21 program to ensure effective identification and evaluation of deviations and failures to comply associated with a substantial safety hazard
 - Include guidance to meet the timeliness evaluation, reporting and notification requirements
- Failure to include 10 CFR Part 21 applicability in procurement documents to Appendix B suppliers

Notices of Nonconformance

- **Design Control:**
 - Failure to perform independent verification and validation of design calculations
 - Failure to document design changes and engineering design review conclusions
- **Instructions, Procedures, And Drawings:**
 - Failure to develop adequate procedures
 - Failure to implement procedural guidance

Notices of Nonconformance

- **Control of Purchased Material, Equipment, and Services:**
 - Failure to include objective evidence in audit reports to support conclusions
 - Failure to verify suppliers' control of M&TE
- **Test Control:**
 - Failure to adequately implement testing activities
 - Inadequate qualification of testing personnel

Notices of Nonconformance

- **Control of Measuring and Test Equipment (M&TE):**
 - Failure to have historical records of calibrations performed
 - Failure to include checklists in the external audit reports of commercial calibration services
- **Handling, Storage, and Shipping:**
 - Failure to have adequate separation of non-stainless steel material
 - Use of unqualified (not nuclear) taping material
 - Failure to monitor temperature and humidity for items as required by purchase orders
- **QA Records:**
 - Failure to specify requirements for the storage and preservation of QA records

Notices of Nonconformance

- **Nonconformance and Corrective Action:**
 - Failure to have adequate procedures
 - Failure to provide adequate procedural guidance for:
 - The review of corrective actions to determine if they are being completed in a timely fashion
 - Establishing significance levels of nonconformances and prioritizing the associated corrective actions
 - Failure to initiate a corrective action report after repetitive nonconformances were identified

Notices of Nonconformance

- **Nonconformance and Corrective Action (cont.):**
 - Failure to initiate a corrective action report after notification of a nonconforming condition by a customer
 - Failure to have sufficient evidence to support the closure of nonconforming conditions
 - Ineffective corrective action and nonconformance control programs:
 - Did not require documentation of conditions adverse to quality
 - Did not require verification that the recommended corrective action was verified to be satisfactory and complete

Notices of Nonconformance

- **Commercial Grade Item Dedication:**
 - Failure to identify and verify critical characteristics
 - Sampling plan not followed for minimum inspection activities
 - Failure to have adequate documented basis to support sampling plan
 - Inadequate surveys - did not include verification of suppliers' control of critical characteristics (e.g., heat/lot/batch control)
 - Inadequate procurement documents - did not impose specific quality requirements for the control of identified critical characteristics
 - Inadequate use of EPRI-5652, Method 4 (Performance History)
 - Dedication Procedure did not include the appropriate 10 CFR 21.3 definition for a commercial grade item as it applies to nuclear power plants licensed pursuant to 10 CFR Part 50

NUPIC Audit Observation

- NRC staff used IP43005, “NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements”
- IP43005 Purpose:
 - Assess the NUPIC QA audit process used for suppliers of components to the nuclear industry
 - Inspect the 10 CFR Part 21 program of the supplier
- Third Party Oversight
 - Cameron Measurement Systems, 8/2007
 - Flowserve Pump Division, 10/2007
 - RPT Audit, 3/2008

International Cooperation

- Interaction with counterparts in several areas, including:
 - Joint activities conducted with Canadian, Finnish, French, German, Korean, and Japanese regulators
 - NRC inspector rotation at STUK and Olkiluoto 3 in Finland
 - Observation of United Kingdom regulator interactions regarding General Electric and Westinghouse Designs
 - Observation of Korean Institute of Nuclear Safety (KINS) inspections at Crosby Valve and Westinghouse Newington

International Cooperation

- Potential to leverage international regulatory oversight of vendors
 - Understand international regulators' vendor oversight requirements and programs
 - Apply the lessons learned through implementation of the international regulators' vendor oversight activities
 - Identify differences with U.S. regulations and programs
 - Plan U.S. vendor inspections using insights from international regulators' observations and findings of vendor activities
 - Obtain construction experience insights

International Cooperation

- January 2008 – Technical exchange visit with KINS
- March 2008 – Observed three vendor inspections performed by Autorité de Sûreté Nucléaire (ASN)
 - Velan Value Co.– SR valves for nuclear industry
 - Cruesot Forge – Large component forgings (SGs, Rx Vessels, Piping)
 - AREVA Chalon Facility – Fabricators of (SGs, Rx Vessels, major components.
- May 2008 – Inspection at MHI with Japan Nuclear Energy Safety (JNES) Organization observation
- May 2008 – Conducted the first ever parallel inspection at Doosan with Korean Institute of Nuclear Safety (KINS) with ASN observation

International Cooperation

- During February 19-22, 2008, the MDEP meeting in Paris established the Multinational Vendor Inspection Programme (MNVIP) Working Group on Component Manufacturing Oversight
- On April 21-22, 2008, the MNVIP Working Group meeting discussed, among other things, the project plan, including the objectives, scope, roles and responsibilities, deliverables, and milestone schedule dates.

Commercial Grade Calibration Services

- NRC Letter to:
 - ACLASS Accreditation Services dated December 19, 2007 (ML073440472)
 - Laboratory Accreditation Bureau (L-A-B) dated April 22, 2008 (ML081140564)
 - International Accreditation Services (IAS) dated May 14, 2008 (ML081330253)
- Bases for NRC approval for accepting ACLASS, L-A-B, and IAS calibration services as an alternative method for qualifying suppliers in lieu of supplier audit, commercial-grade survey, or in-process surveillance for commercial-grade suppliers of calibrations services.
- Similar to Arizona Public Services safety evaluation report dated September 28, 2005, for NVLAP and A2LA. (ML052710224)

ASME NQA-1/NRC interactions

- NRR staff is in the initial stages of developing a revision to Regulatory Guide 1.28 for potential endorsement of the NQA-1-2008 Edition
- NQA-1 task group and NRC staff have resolved commercial grade dedication issues for the Part II, Subpart 2.14
- NQA-1 Task Group continues to address software QA issues for revision and inclusion in the NQA-1-2009 addenda

Generic Communications

- Information Notice 2007-40:
 - Informed addressees about recent NRC findings involving the inadequate implementation of 10 CFR Part 21 by vendors that supply basic components such as materials, equipment, components, or services to be used in NRC-licensed facilities
- Information Notice 2008-04:
 - Informed addressees of the potential for counterfeit parts that could enter their supply chains
- NRR/NRO Quality Assurance Website:
<http://www.nrc.gov/reactors/new-licensing/quality-assurance.html>

Suspect, Counterfeit & Fraudulent Parts

- Licensees are held accountable for the quality of parts used in the construction of new reactors
- GL 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products”
- Information Notice 2008-04, “Counterfeit Parts Supplied to Nuclear Power Plants,” issued April 2008
- Potential inspection focus areas:
 - Procurement and commercial-grade dedication programs to ensure the quality of procured vendor products
 - Industry practices for identifying counterfeit or fraudulent parts
 - Documents that provide traceability for quality-related components
 - Supply chain for a sample of specific components provided to each new reactor project

Number of Nuclear Companies with ASME Certificates

Year	Components		Materials		Total
	Domestic	International	Domestic	International	
1982	386	49	95	54	584
2005	78	50	23	16	167

Reminder

- Vendors should be fully knowledgeable of all regulatory requirements and technical specifications imposed by licensees in purchase orders
- Licensees should work with their vendors to ensure that the vendor quality programs adequately implement the requirements imposed in the purchase orders

Questions?